

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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March 20, 2014

Dr. John C. Martin, PhD
Chief Executive Officer
Gilead Sciences Inc.
333 Lakeside Drive
Foster City, CA 94404

Dear Dr. Martin:

We are writing to request a briefing from Gilead Sciences Inc. to answer important questions about the pricing of the company's recently approved Hepatitis C drug, Sovaldi.

A breakthrough treatment for Hepatitis C could result in significant public health benefits. Approximately 3.2 million Americans have a chronic Hepatitis C infection, and the illness causes approximately 15,000 deaths in the United States annually.¹ There is no vaccine for Hepatitis C, which causes fatal cirrhosis or liver cancer in up to 5% of affected individuals.²

There is evidence that Sovaldi could be a breakthrough treatment. According to FDA, "Sovaldi was effective in treating multiple types of the hepatitis C virus. ... demonstrat[ing] efficacy in participants who could not tolerate or take an interferon-based treatment regimen and in participants with liver cancer awaiting liver transplantation, addressing unmet medical needs in these populations."³

¹ CDC, Hepatitis C FAQs for the Public (2014) (online at <http://www.cdc.gov/hepatitis/c/cFAQ.htm#statistics>); New York Times, *Awareness: Hepatitis C Death Rate Creeps Past AIDS* (Feb. 27, 2014) (online at www.nytimes.com/2012/02/28/health/research/hepatitis-c-deaths-creep-past-aids-study-finds.html?_r=1&).

² CDC, Hepatitis C FAQs for the Public (2014) (online at <http://www.cdc.gov/hepatitis/c/cFAQ.htm#statistics>); New York Times, *Awareness: Hepatitis C Death Rate Creeps Past AIDS* (Feb. 27, 2014) (online at www.nytimes.com/2012/02/28/health/research/hepatitis-c-deaths-creep-past-aids-study-finds.html?_r=1&).

³ FDA, FDA Approves Sovaldi for Chronic Hepatitis C (Dec. 6, 2013) (online at <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm377888.htm>).

Our concern is that a treatment will not cure patients if they cannot afford it. Reports indicate that Gilead intends to sell Sovaldi at \$84,000 per treatment.⁴ In cases where Sovaldi is prescribed with other treatments the costs could be even higher. According to a recent Reuters report, “many doctors are requesting a \$150,000 combination of Sovaldi ... and Olysio.”⁵

These costs are likely to be too high for many patients, both those with public insurance and those with private insurance.⁶ Because Hepatitis C is “concentrated in low-income, minority patients,” the affordability problems are likely to be particularly acute for state Medicaid programs and those patients served by these programs.⁷ Colorado and Pennsylvania have already announced that their Medicaid programs will be limiting use of the new drug to “only the sickest patients,” such as those already suffering from liver disease.⁸ California’s Medicaid program is still considering how and when to reimburse for the drug.⁹ The large pharmacy benefit manager Express Scripts has said it is “encouraging some doctors in its networks to delay prescribing Sovaldi.”¹⁰ Even in cases where public or private insurers pay for the medication, it will impose substantial costs on taxpayers and could cause premium increases for those with employer or individual coverage.

The extraordinarily high cost of your drug raises additional concerns because of the role of the federal government in speeding its approval. In April 2013, Gilead submitted a New Drug Application to the Food and Drug Administration for approval of Sovaldi for the treatment of Hepatitis C. As part of the request, Gilead filed for and received a Priority Review and Breakthrough Therapy designation, which reduces the FDA review goal date from ten to six

⁴ Washington Post, *Costly Hepatitis Drug Sovaldi Rattles Industry* (Mar. 1, 2014) (online at http://www.washingtonpost.com/national/health-science/costly-hepatitis-drug-sovaldi-rattles-industry/2014/03/01/86cab0b4-a091-11e3-9ba6-800d1192d08b_story.html).

⁵ Reuters, *Insurers, Medicaid fear multibillion-dollar hepatitis C drug tab* (Mar. 4, 2014) (online at www.reuters.com/article/2014/03/04/us-health-hepatitis-idUSL1N0M10Z720140304).

⁶ Bloomberg, *At \$84,000 Gilead Hepatitis C Drug Sets Off Payer Revolt* (Jan. 27, 2014) (online at <http://www.bloomberg.com/news/2014-01-27/at-84-000-gilead-hepatitis-c-drug-sets-off-payer-revolt.html>).

⁷ Bloomberg, *Hepatitis C Drug Price Limiting State Medicaid Approvals* (Mar. 5, 2014) (online at www.bloomberg.com/news/2014-03-05/hepatitis-c-drug-price-limiting-state-medicaid-approvals.html).

⁸ *Id.*

⁹ Reuters, *Insurers, Medicaid fear multibillion-dollar hepatitis C drug tab* (Mar. 4, 2014) (online at www.reuters.com/article/2014/03/04/us-health-hepatitis-idUSL1N0M10Z720140304).

¹⁰ Washington Post, *Costly Hepatitis Drug Sovaldi Rattles Industry* (Mar. 1, 2014) (online at http://www.washingtonpost.com/national/health-science/costly-hepatitis-drug-sovaldi-rattles-industry/2014/03/01/86cab0b4-a091-11e3-9ba6-800d1192d08b_story.html).

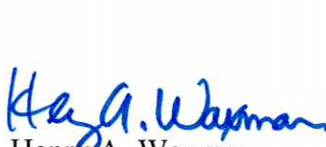
months.¹¹ This designation is awarded to medicines that meet certain criteria, including “that the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.”¹² The FDA approved Sovaldi on an expedited basis on December 6, 2013.¹³


This history raises many questions about Gilead's approach to pricing this drug and the impact the high cost may have on public health. In order to address these issues, we ask that you brief Committee staff on a number of key questions, including:

- (1) The methodology used by Gilead to establish Sovaldi's pricing.
- (2) The extent to which Gilead is providing discounts to low-income patients and to key government or private-sector purchasers of the drug.
- (3) The value to the company of the expedited review provided under the Priority Review and Breakthrough Therapy designation and how any savings provided by the expedited review factored into pricing decisions for the drug.
- (4) The public health impact of insurers' and public health programs' decisions not to cover Sovaldi for all patients with Hepatitis C.

We ask that you provide this briefing no later than April 3, 2014. Please contact Brian Cohen of the Committee staff at (202) 225-3641 if you have any questions.

Sincerely,


Henry A. Waxman
Ranking Member


Frank Pallone, Jr.
Ranking Member
Subcommittee on Health


Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

¹¹Food and Drug Administration, *Regulatory Information* (online at www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdact/significantamendmentstothefdcact/fdasia/ucm341027.htm).

¹² *Id.*

¹³ Food and Drug Administration, *FDA Approves Sovaldi for Chronic Hepatitis C* (press release) (Dec. 6, 2013) (online at www.fda.gov/newsevents/newsroom/pressannouncements/ucm377888.htm).